

### **IN THE DRAWINGS**

Fig. 29 (drawing Page 11) of the drawings has been amended to include reference numerals and lead lines identifying catheter and stylet assembly components illustrated in paragraph [00102] of the specification. A copy of the drawing page in question, including red ink amendments, is attached. A replacement Page 11 of the formal drawings will be filed upon receipt of the Examiner's approval.

## REMARKS

Initially, with respect to the "Priority" and "Specification" objections and/or rejections contained in numbered paragraphs 2 and 3 of the Office Action, applicant respectfully disagrees and traverses them. Referring to the disclosure of application Ser. No. 10/764,674, the Examiner's attention is invited to numbered paragraphs [0013] and [00109]. There, the disclosure describes the use of "a small, very flexible 8 Fr feeding tube" and the fact that the "invention is described in the context of a standard polyurethane feeding tube." Referring to PCT Application No. U.S. 03/02347 and Provisional U.S. Application No. 60/351,698, (page 4, lines 5-9 of the former and page 3, lines 22-27 of the latter), the catheter tube disclosed in each case are described as containing "urethane", i.e., plastic. In the "Summary" section of these priority applications, "the use of a small, very flexible 8 Fr feeding tube" is described. "Very" means "exceedingly" flexible, as stated in various dictionary sources. Accordingly, paragraph 2 and 3 objections/rejections should be withdrawn.

On the subject of 35 U.S.C. § 103(a) rejections, Claims 7-14 and 30-39 have been rewritten in amended form as new Claims 40-50 to more clearly define the application's invention. For the following reasons, applicant respectfully submits that new Claims 40-50 should now be in allowable form.

In considering applicant's combination catheter and insertion assembly as claimed to date, nine (9) prior art references were treated by the Examiner. Those references, in order of their asserted significance, are the Pozzo, Ferguson et al., Abrahamson et al., Preissman, et al., Quinn ('539), Anderson et al., Meier et al., Clegg et al. and Osborne U.S. patents.

Pozzo discloses an enteral feeding catheter and stylet assembly. The catheter tube contains a single lumen tube and a bolus tip at the distal end of the single lumen tube. A braided wire stylet has a plastic sleeve extending partially over it. The stylet extends through the single lumen tube to aid in inserting the catheter to the stomach or duodenum of the patient. The assembly does not contain a dual lumen tube, much less a dual lumen tube coupled to a single lumen tube by a mid-port bolus. The assembly

does not contain a dual stylet stiffener arrangement much less a stiffener wire which extends through the two feeding lumens of the catheter.

Ferguson et al. discloses a “balloon” catheter utilized primarily for vascular insertion. The catheter contains a multiple lumen tube containing an infusion lumen, a guide wire lumen and a stylet lumen. The catheter is not designed for, nor suited for, naso-enteral feeding through aligned feeding lumens connected by a mid-port bolus. The catheter tube contains multiple lumens useable for threading independently a guide wire, and/or multiple stylets.

Abrahamson et al. also discloses a catheter and insertion stiffener assemblies for introducing a catheter tube into a blood vessel. The catheter tube contains a wire stiffener having different flexibility segments. It also contains a guide wire.

Preissman et al. does not even relate to a catheter, much less an enteral feeding catheter. It relates to a instrument for performing percutaneous implantation of hand tissue implant materials. A cannula includes an elongated tube through which a “depth-guarded” stylet is inserted.

Quinn is one of the inventor’s own inventions. It discloses a “hemodialysis”, catheter, i.e., a blood vessel catheter. The catheter is unrelated to enteral feeding and unrelated to catheter tube insertion of any kind, much less stylet manipulation of a catheter tip bolus. No combination of a dual lumen and a single lumen connected by a mid-port bolus is taught or suggested.

Andersen et al. discloses an enteral feeding catheter wherein nutrients or medicaments are delivered directly to a patient’s stomach or duodenum through a nasogastrointestinal tube. The catheter does not utilize a jejunal feeding tube or feeding port. It does comprise a dual lumen tube containing a feeding lumen and a gastric relief lumen, the feeding lumen connected at a mid-port bolus to a single feeding tube which is long enough to extend through the duodenum into the jejunum, the mid-port bolus also containing a gastric relief port connection to the gastric relief lumen.

Meier et al. does disclose a gastrojejunal feeding system. However, the feeding system does not comprise a nasogastroenteral introduced tube. The Meier et al. tube contains a feeding lumen inserted through a stoma in the patient’s stomach and, also, a gastric relief lumen for stomach gas relief. The tube, which extends from the patients

stomach past the pylorus and through the duodenum to the jejunum, may have a coiled configuration to assist in retaining the distal end of the tube in the jejunum.

Clegg et al. discloses a device for creating a stomach stoma for placement of a feeding tube. The device other relates to a conventional feeding tube used to supply various fluids into the stomach or small bowel of a patient.

Osborne discloses a gastrojejunostomy catheter including a distal portion of a feeding tube which can be positioned in the jejunum.

The rejections of Claims 7-14 and 39-39 are all based on 35 U.S.C. § 103(a), relying primarily on Pozzo in view of Ferguson et al. and others, including Quinn. The shortcomings of their references are detailed above. Only with the hindsight of the applicant are the presently claimed inventions suggested.

The Examiner relies greatly on the decision in St. Regis Paper Co. v. Bemis Co., 193 U.S.P.Q 8 (7<sup>th</sup> Cir. 1977), for the proposition that the mere duplication of essential working parts of a device involves only routine skill in an art. Applicant, submits, however, that St. Regis is not in point for two important reasons. First, the decision was rendered in the context of the "synergism" test on which the case turned, and that standard has been overturned. Second, taken individually or collectively, the references not only do not suggest applicant's claimed inventions, they actually rely on the hindsight of the applicant's teachings.

Respectfully submitted,

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Attachment: Drawing Page 11

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